CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11430	Date: May 24, 2022
	Change Request 12667

This Transmittal is no longer sensitive and is being re-communicated. This instruction may now be posted to the Internet. Transmittal 11347, dated April 7, 2022 is being rescinded and replaced by Transmittal 11430, dated May 24, 2022 to move from Publication 100-20 (One Time Notification) to Publication 100-04 (Standard) to include an update to the Medicare Claims Processing Manual. The manual section, Publication 100-04, Chapter 32, Section 411.3 and Attachment A, table 3 are being updated to include a named HCPCS drug J1551, Cutaquig. All other information remains the same.

SUBJECT: Update to 'J' Drug Code List for Billing Home Infusion Therapy (HIT) Services

I. SUMMARY OF CHANGES: The purpose of this change request is an update to the guidance and claims processing systems changes necessary to implement of Section 5012(d) of the 21st Century Cures Act, and to detail necessary changes to those systems and processes to include a newly assigned HCPCS drug code for payment beginning July 1, 2022.

EFFECTIVE DATE: July 1, 2022

*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: July 5, 2022

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/411.3 Home Infusion Drugs: Healthcare Common Procedural Coding System (HCPCS) Drug Codes

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements Manual Instruction

Attachment - Business Requirements

 Pub. 100-04
 Transmittal: 11430
 Date: May 24, 2022
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SUBJECT: Update to 'J' Drug Code List for Billing Home Infusion Therapy (HIT) Services

EFFECTIVE DATE: July 1, 2022

*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: July 5, 2022

I. GENERAL INFORMATION

A. Background: Section 5012(d) of the 21st Century Cures Act (Pub. L 144-255) amended sections 1861(s)(2) and 1861(iii) of the Social Security Act (the Act), requiring the Secretary to establish a new Medicare home infusion therapy services benefit. The Medicare home infusion therapy services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy services and home infusion drugs furnished by a qualified home infusion therapy supplier.

Section 1861(iii)(3)(C) of the Act defines "home infusion drug" as a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in section 1861(n) of the Act). Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list.

B. Policy: As described in the 21st Century Cures Act, a separate payment for home infusion therapy services will be made under the permanent home infusion therapy benefit to qualified home infusion suppliers, effective January 1, 2021.

Home infusion drugs are assigned to three payment categories, as determined by the Healthcare Common Procedure Coding System (HCPCS) J-code. Payment category 1 includes certain intravenous antifungals and antivirals, uninterrupted long-term infusions, pain management, inotropic, chelation drugs. Payment category 2 includes subcutaneous immunotherapy and other certain subcutaneous infusion drugs. Payment category 3 includes certain chemotherapy drugs. CMS continues to use the G-codes previously established for the professional services furnished on an infusion drug administration calendar day for each payment category.

This Change Request (CR) updates the list of home infusion drugs to add J1551 to payment category 2. The corresponding G-codes for category 2 drugs are G0069 or G0089.

Because all home infusion therapy drugs are now assigned unique J-codes, we do not expect many supplier-claims for home infusion therapy services related to a Not-Otherwise Classified (NOC) drug code. However, we expect the payment categories to continue to be determined by the contractor only for any other new home infusion drug additions

to the Local Coverage Determination (LCD) for External Infusion Pumps (L33794). Suppliers should also continue to identify the name of the new drug in the comment section (data element 2400/SV101-7 of the 837P or Item 19 of the CMS-1500) of the professional service claim for the corresponding home infusion therapy service G-code.

Please refer to CRs 11880, 12108, and 12324 for more detailed policy and billing information for home infusion therapy services.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Re	Responsibility											
			A/B	}	D	;	Sha	red-		Other				
		N	MA(M		-	tem						
									Е	Maintainers			ers	
		A	В			F	M	V	C					
				Н	M	_	C	M	W					
				Н	A	S	S	S	F					
					C	S								
12667.1	Effective for professional claims with dates of service on or after July 1, 2022, contractors shall recognize and update current logic when a claim has HCPCS 'G0069' or 'G0089' and there is no durable medical equipment claim in history with J1551 within 30 days prior to the incoming Date of Service. NOTE: This edit shall have override capability at the claim detail line.		X						X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spoi	nsib	ility	
			A/B MA(D M E	C E D
		A	В	H H H	M A C	I
12667.2	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.		X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Yvette Cousar, 410-786-2160 or Yvette.cousar@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

411.3 Home Infusion Drugs: Healthcare Common Procedural Coding System (HCPCS) Drug Codes

(Rev. 11430; Issued: 05-24-22; Effective: 07-01-22; Implementation: 07-05-22)

The home infusion therapy services payment is intended to cover the professional services needed for the administration of certain home infusion drugs covered as supplies necessary for the effective use of external infusion pumps. This payment separately and explicitly pays for the services related to the administration of the drugs identified on the DME LCD for External Infusion Pumps, when such services are furnished in the individual's home. Section 1861(iii)(3)(C) of the Act defines "home infusion drug" as a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in section 1861(n) of the Act). Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list.

Home infusion drugs are assigned to three payment categories, as determined by the HCPCS J-code. Payment category 1 includes certain intravenous antifungals and antivirals, uninterrupted long-term infusions, pain management, inotropic, chelation drugs. Payment category 2 includes subcutaneous immunotherapy and other certain subcutaneous infusion drugs. Payment category 3 includes certain chemotherapy drugs. CMS will continue to use the G-codes, established for the temporary transitional payments in CYs 2019 and 2020, for the professional services furnished on an infusion drug administration calendar day for each payment category. CMS has established a single payment amount for each of the three categories for professional services furnished for each infusion drug administration calendar day. Each payment category will be paid at amounts in accordance with infusion codes and units for such codes under the physician fee schedule for each infusion drug administration calendar day in the individual's home for drugs assigned to such category. The payment amounts are equal to 5 hours of infusion therapy in a physician's office. Further policy information can be found in Publication 100-02, Chapter 15, Section 320.

Category	1
J-Code	Description
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg

J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg
Category 2	2
J-Code	Description
J1551 JB	Injection, immune globulin (cutaquig), 100mg
J1555 JB	Injection, immune globulin (cuvitru), 100 mg
J1558 JB	Injection, immune globulin (xembify), 100mg
J1559 JB	Injection, immune globulin (hizentra), 100mg
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g. liquid), 500 mg
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
<i>J7799 JB</i>	This NOC code may be used to identify the subcutaneous immune globulin (cutaquig)
Category 3	
J-Code	Description
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg
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It is important to note that this list is not static. The payment category may be determined by the contractor for any new home infusion drug additions to the Local Coverage Determination (LCD) for External Infusion Pumps as identified by the following not-otherwise-classified (NOC) codes:

- J7799 Not otherwise classified drugs, other than inhalation drugs, administered through **DME**
- J7999 Compounded drug, not otherwise classified.

Attachment A: Billing for Home Infusion Therapy Services on or After January 1, 2021

Table 1 shows the time increments providers should report visit length in 15-minute increments (15 minutes = 1 unit). See the table below for the rounding of units:

Table 1: Time Increments

Unit	Time
1	<23 minutes
2	= 23 minutes to <38 minutes
3	= 38 minutes to <53 minutes
4	= 53 minutes to <68 minutes
5	= 68 minutes to <83 minutes
6	= 83 minutes to <98 minutes
7	= 98 minutes to <113 minutes
8	= 113 minutes to <128 minutes
9	= 128 minutes to <143 minutes
10	= 143 minutes to <158 minutes

Table 2 shows the use of the three G-codes established for the home infusion therapy benefit, and reflects the therapy type and complexity of the drug administration.

Table 2: Payment Categories for Home Infusion Therapy Professional Services (G-Codes)

	Category 1	Category 2	Category 3
Description	Intravenous anti-infective, pain management, chelation, pulmonary hypertension, inotropic, and other certain	Subcutaneous immunotherapy and other certain Subcutaneous infusion	Chemotherapy and other certain highly complex
G-Code	intravenous infusion drugs	drugs	intravenous drugs
Initial Visit	G0088	G0089	G0090
Subsequent Visit	G0068	G0069	G0070

Table 3 provides a list of J-codes associated with the home infusion drugs that fall within each category.

Table 3: Payment Categories for Home Infusion Drugs (J-Codes)

	Category 1		
J-Code	Description		
J0133	Injection, acyclovir, 5 mg		
J0285	Injection, amphotericin b, 50 mg		
J0287	Injection, amphotericin b lipid complex, 10 mg		
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg		
J0289	Injection, amphotericin b liposome, 10 mg		
J0895	Injection, deferoxamine mesylate, 500 mg		
J1170	Injection, hydromorphone, up to 4 mg		
J1250	Injection, dobutamine hydrochloride, per 250 mg		
J1265	Injection, dopamine hcl, 40 mg		
J1325	Injection, epoprostenol, 0.5 mg		

J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg

J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg
	Category 2
J-Code	Description
J1551 JB	Injection, immune globulin (cutaquig), 100mg
J1555 JB	Injection, immune globulin (cuvitru), 100 mg
J1558 JB	Injection, immune globulin (xembify), 100mg
J1559 JB	Injection, immune globulin (hizentra), 100mg
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g. liquid), 500 mg
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
<i>J7799 JB</i>	This NOC code may be used to identify the subcutaneous immune globulin (cutaquig)
	Category 3
J-Code	Description
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

The payment category may be determined by the contractor for any new home infusion drug additions to the Local Coverage Determination (LCD) for External Infusion Pumps as identified by the following not- otherwise-classified (NOC) codes:

- J7799 Not otherwise classified drugs, other than inhalation drugs, administered through DME
- J7999 Compoundeddrug, not otherwise classified